Valence Robotic Navigation System

IFU

Part Number 525-412 Instructions For Use, Revision A

TABLE OF CONTENTS

GENERAL INFORMATION

The Valence Robotic Navigation System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard surgical instruments, based on an operative plan and feedback from an image-guided Workstation with 3D imaging software.

The Valence Robotic Navigation System is installed by qualified ATEC personnel only. If you have any questions about your system installation, contact ATEC (see contact information section). There are no recommended settings or configurations for the system interface except the input/output connections described in the Valence Operator Manual.

The intended user profile for the Valence Robotic Navigation System is the operating room staff during the procedure (including spine surgeons, nurses, and clinical support specialists). The users should be familiar with the clinical procedure. The Valence Robotic Navigation System should be used only by qualified medical professionals who are thoroughly trained in use of the system. Users will be trained by ATEC personnel using the system's Valence Operator Manual for guidance. Users will be trained in-person using a production or production representative system and instrumentation. The intended patient population for the system are patients for whom stereotactic image guided pedicle screw placement is appropriate.

INDICATIONS FOR USE

The Valence Robotic Navigation System is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of tracked instruments to be used by surgeons for navigating and/or guiding surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan. The Valence Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the ATEC Invictus® Spinal Fixation System.

CONTRAINDICATIONS

The system should not be used for any medical conditions which may contraindicate the medical procedure itself.
The system should not be used with any surgical tables other than the Allen Advance, Jackson Table, or equivalent surgical tables.
High-Frequency (HF) surgery devices in the vicinity of the device are contraindicated.

WARNINGS AND PRECAUTIONS

⚠ WARNING: The system may only be used by medical professionals.

⚠ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING: The power cord may not be extended by an extension cord since this increases the resistance of the protective earth and may result in electric shock. For the U.S.A. and other countries with dedicated medical grade power outlets, connection of the system is only allowed to a power outlet that provides a protective earth connection marked as “MEDICAL GRADE” or “HOSPITAL GRADE.”

⚠ WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING: To avoid the risk of electrical shock, this equipment must only be connected to the supply mains with protective earth.

⚠ WARNING: Avoid the following situations because they may compromise the integrity and efficacy of the sterile drapes:

- Rough handling, such as extreme pull and push forces or binding with moving parts
- Touching non-sterile surfaces with the drape
- Close proximity of sharp instruments to the drape

⚠ WARNING: The use of instrumentation, interfaces, and sterile drapes other than stated compatible instruments, interfacing devices, and sterile drapes may lead to loss of accuracy, patient injury, or both.

⚠ WARNING: Do not use equipment if there is any possible damage to the equipment.

⚠ WARNING: The use of system components beyond their 7 years useful life or if physically damaged may lead to patient injury.

⚠ WARNING: The repair or modification of the system components or surgical instruments by anyone other than qualified service personnel may compromise the product’s ability to perform effectively and void the equipment warranty.

⚠ WARNING: Be aware of risks when using HF (high frequency) electrosurgery devices, such as monopolar or bipolar needles or forceps, together with the system. Hazardous voltage may be induced to the system. Risk of electrical shock or thermal injuries.

⚠ WARNING: Do not use HF (high frequency) electrosurgery devices, such as monopolar or bipolar needles or forceps, with maximum output voltages higher than 6 kV (peak-to-peak) together with the system. Hazardous voltage may be induced to the system, with the risk of causing of electrical arcs, electrical shocks, or thermal injuries.

⚠ WARNING: Instruments designed for reuse in the sterile field, such as the Registration Array; Navigated Guide Tube; Navigated Guide Tube, NM; Awl; Awl Tap Cap; Instrument Tracker; Slap Hammer; 4.5mm Tap; 5.5mm Tap; 6.5mm Tap; 7.5mm Tap; Tissue Protector; Tissue Protector, NM; Insulating Sleeve; Navigated Dilator; Polyaxial Screwdriver; Reduction Screwdriver; Modular Shankdriver; 8mm Hex Driver, Reference

Link; Camera Shroud; and Scalpel Handle are supplied non-sterile. Clean and sterilize these instruments before every use in accordance with the Sterilization Instructions.

⚠ WARNING: Connecting the system to non-approved IT networks and other equipment can result in previously unidentified risks to patients, operators, or third parties. The system must only be connected to a compatible 3D imaging system. Log files within the system will be maintained to verify proper setup. The responsibility for the identification, analysis, evaluation, and control of risks associated with connecting the system to a non-approved IT network resides with the individuals performing the connection.

⚠ WARNING: Changes to the IT network can introduce new risks to the product that require additional analysis. These changes encompass changes in network configuration, connection of additional items, disconnection of items, or upgrade of equipment. Log files within the system will be maintained to verify proper setup. Individuals implementing changes on the IT network are responsible for the identification, analysis, evaluation, and control of risks associated with the changes.

⚠ WARNING: The only way to disconnect the system from mains power is by unplugging the power cord from the mains power outlet. Disconnection of the mains plug will not interrupt the internal PC battery.

⚠ WARNING: Do not plug the power cord in such a way that it may lead to a difficult disconnection from power in case of major system fault. Doing so may result in patient injury. Protect the cable from potential damage.

⚠ WARNING: If the system navigation appears inaccurate and recommended steps to restore accuracy are not successful, abort the use of the system. Proceeding with possibly inaccurate navigation may result in patient injury.

⚠ WARNING: All input/output cables on the computer must remain connected at all times and the protective cover for the computer input/output panel must remain secured in place at all times. Only qualified ATEC personnel should remove the protective cover and/or connect or disconnect any I/O cables from the I/O panel during installation or service.

⚠ WARNING: Only connect the 3D imaging system to the isolated network receptacle on the back of the System Cart. Do NOT connect other non-compatible imaging devices, the hospital PACS, or other network devices.

⚠ WARNING: Unused electronic interfaces found on the device are not meant for connecting to other medical devices or non-medical device technologies. These interfaces are reserved for ATEC service technicians for maintenance purposes.

⚠ WARNING: Do not use a Targeting Platform with broken housing or covers. Sharp edges of a defective Targeting Platform housing or covers may cause failures such as user injury or a breach of sterile drapes.

⚠ WARNING: Before starting the surgical procedure, make sure that the Positioning Arm and Targeting Platform are very securely connected and can withstand procedural forces that may cause arm joint slippage or instability. Unstable connection and joint looseness may increase the possibility of patient injury.

⚠ WARNING: Visually inspect each surgical instrument for physical damage/wear prior to surgical use:

- There should be no corrosion or pitting of the surface on any instrument.
- The pointed ends of the Awl and Taps should be sharp and not bent.
- The shafts of all linear instruments should be straight and not bent.

- The Screwdriver shaft should turn freely within the Driver cage.
- The interior bore and outer surface of the Navigated Guide Tube should be free of burrs or other obstructions such that the Awl and each Tap can be inserted and removed easily.
- The interior bore of the Navigated Guide Tube should be free of burrs or other obstructions such that Instruments and Sleeves can be inserted and removed easily.
- The outer surface of the Navigated Guide Tube should be free of burrs or other damage such that it can be inserted into the Guide Tube Assembly and easily removed.
- Report any instrument damage to the surgical staff to further assess functionality and useful life.

⚠ WARNING: Remove any surgical tools or instruments from the Guide Tube Assembly before moving the Targeting Platform. Instruments mounted to the Guide Tube Assembly during movement of the Targeting Platform may increase the possibility of patient injury.

⚠ WARNING: Movements are canceled when the Move Enable button is released. Failing to hold the Move Enable button for the complete course of movement may cause delays to the procedure or inadvertent inaccurate positioning of the Guide Tube Assembly.

⚠ WARNING: Any potential collisions between the Guide Tube Assembly and the patient's anatomy should be observed and avoided. Inadvertent contact with the patient may increase the possibility of navigation inaccuracy or patient injury.

⚠ WARNING: Ensure proper gross positioning of the Targeting Platform at the beginning of the surgical procedure. Inadequate gross positioning may prevent the system from being able to align with the active surgical plan, increasing the possibility of patient injury or a compromised surgical procedure.

⚠ WARNING: Always consult the Workstation Navigation System display for current trajectory alignment information. Alignment information at Targeting Platform may be outdated. Failure to consult the Workstation Navigation System display may increase the possibility of patient injury or a compromised surgical procedure.

⚠ WARNING: Do not correct a misaligned trajectory position while a surgical tool is inserted in the Guide Tube Assembly or touching the patient anatomy. Remove any surgical tools before automatic or manual movements of the Targeting Platform. Surgical tools mounted in the Guide Tube Assembly during movement of the Targeting Platform may cause injuries.

⚠ WARNING: The equipment must only be used with power cords supplied by ATEC that are approved for use in the United States. Failing to do so may result in patient injury and/or improper system operation.

⚠ WARNING: Some system components contain batteries. Do not recharge or disassemble batteries that have been removed from system components. Observe local regulations concerning battery disposal.

⚠ CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

⚠ CAUTION: Exceeding the maximum length of any external cables attached to the interfaces of the system (especially the network cable) may have impact on the electromagnetic performance and compliance (immunity or emission) of the system.

Shielded CAT6e cables up to 10m have been tested and did not show any compliance issues.

⚠ CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12in) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTION: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

⚠ CAUTION: Connecting the system to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. Users should identify, analyze, evaluate, and control these risks. Subsequent changes to the network could reduce the functionality of the system or introduce new risks, and therefore require additional analysis.

⚠ CAUTION: The network connections between system elements must only be established directly, without use of any hub, switch, router, or equivalent device, to avoid any impact on performance.

⚠ CAUTION: The power cord should be readily accessible to allow for easy disconnection from power, in case of major system fault. Protect the cable from potential damage.

⚠ CAUTION: Do not use a Targeting Platform with a broken housing or broken cover tape. A defective Targeting Platform housing or covers may cause functional or motion impairment, and the impairment may delay the surgical workflow.

⚠ CAUTION: Check for sufficient range of the Targeting Platform relative to the operative site. Adjust the mounting as necessary then lock down the Positioning Arm and Targeting Platform in a near vertical or leaning superior orientation to retain clearance for the 3D imaging system entry path and allow for easier draping.

⚠ CAUTION: If the Registration Array moves during imaging, the system will terminate the registration process and provide the user with an on-screen error message: “The Registration Array Moved.” A new scan is necessary after confirming that the Registration Array is firmly held by the Targeting Platform or well secured relative to the patient.

⚠ CAUTION: Handle the equipment with care to prevent severe or functional damage to the system and a possible reduction in performance.

⚠ CAUTION: Precisely follow the cleaning instructions in the Section “Cleaning Instructions” to prevent ingress of liquid, which may cause severe damage to the electrical equipment or reduce its useful life.

⚠ CAUTION: Do not allow fluid to enter any system enclosure. Do not spray liquids directly on the system. This can lead to equipment damage. Disconnect from power and allow the system to dry if you suspect fluids may have entered any part of the unit.

- Power down and unplug the system before performing cleaning or disinfection procedures.
- Refer to Sterilization Procedure for compatible disinfectants and recommended chemistries. If a premoistened wipe is not available, use a clean wipe and moisten with

the disinfectant. Do not over saturate the wipe so much that liquid can enter openings in the parts to be cleaned.

- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue on the system components. This will help maintain the appearance of the system components.

⚠ CAUTION: For cleaning and disinfecting each of the accessories follow the cleaning process as defined by their manufacturer instructions for use.

⚠ CAUTION: Do not transport the system outside of the specified use environment, as this may lead to system damage.

⚠ CAUTION: If an emergency shutdown is necessary, press and hold the Power button on the Control Unit for at least 1 second (until the screen turns dark) and remove the power plug from the electrical outlet after shutdown.

⚠ CAUTION: If an intraoperative situation requires immediate access to the patient, remove all instruments from the Guide Tube Assembly (if present), unlock the Positioning Arm carrying the Targeting Platform, and reposition it away from the surgical field.

⚠ CAUTION: Keep the ball joints of the Positioning Arm clean. Dirty ball joints could seize, resulting in a risk of delay during surgery.

SOFTWARE AND SECURITY

The system includes features and functionality that facilitate management of security. These features work in conjunction with the security practices of hospitals and clinics to provide safe and secure operation of the system and to protect attached networks and devices.

System Security Functionality

Access control: The system has no user accessible accounts or passwords. Controlling access to the system has the ability to prevent unauthorized user access to the system, the data contained on the system, and other devices that may be networked with the system.

Encryption: The system does not store any information containing patient medical images and surgical plan information when the system is not in use. The system does not transfer data from the system over wireless or wired networks. The only data received by the system is received over a wired network connection from an imaging system. The only data format allowed for transfer to the system is DICOM image data from an imaging system. The data received by the system from the imaging system is not encrypted by the imaging system.

Firewall: Only predefined connections and information are allowed to be passed to the system over network communications. The connection of the system to an imaging system is configured using a static IP address to a specific port address and “AE Title” required by the DICOM image transmission protocol.

Antivirus: There is no antivirus software installed on the system. The system mitigates the possibility of virus entry into the system by limiting external access to only medical imaging systems connected over a wired LAN port, disabling wireless network access, and eliminating user account access and the ability of users to install software.

Best Practices to Maintain Security of the System

Maintain good physical controls over the system. Keep the system in a secure location and environment to prevent unauthorized access and unauthorized modifications to the system.

Only connect the system to managed, secure networks for connections to imaging systems.

Allow only DICOM images from imaging systems to be transmitted to the static IP address and port number of the system.

Allow only authorized ATEC personnel to install any software updates or software patches for security purposes.

Only authorized ATEC personnel may install application software/operating system updates.

If you suspect that the system has been compromised by a security threat, follow these steps:

1. When the system is not in use for a clinical procedure, shut down the system.
2. Disconnect the system from any networks or other devices.
3. Contact ATEC technical support for further assistance in troubleshooting potential security threats.

Network Connection Information
A wired network connection is provided on the system. The wired network connection is used to transfer patient images to the system. The system receives the signaling, protocol and image data from the 3D imaging system. The system transmits only the signaling and protocol information required by the DICOM image transfer protocol to the imaging system.

VALENCE SYSTEM COMPONENTS

The following components make up the Valence Robotic Navigation System:
Targeting Platform: The Targeting Platform receives commands and power from the Control Unit (CU) and informs the CU about current Targeting Platform status (position, eventual problems, software status). The commands are translated into mechanical motion to establish a fixed trajectory for surgical instruments.
End effector: A mechanical fixture that connects through two joints to the frontal interface of the Targeting Platform and translates the Targeting Platform module movement into instrument positioning and angulation.
Positioning Arm: The Positioning Arm facilitates positioning of the Targeting Platform. It is a multi-functional arm for flexible gross-positioning of the Targeting Platform.
Strain Relief Box: Mounted to the side-rail of the operating room table. Distributes power and data to system components and prevents cables from pulling on the Control Unit and Targeting Platform.
Control Unit: Provides motion control of the Targeting Platform. Allows the user to automatically align to the active surgical plan or to manually position the system to any point within the range of motion.
Camera: The single lens camera is a flexible, real-time tracking technology that provides accurate, real-time relative measurements.
System Cart: Storage and primary connections for the Camera and Targeting Platform. Connects and provides power and data interface to the system.

PREOPERATIVE MANAGEMENT

Only patients meeting the criteria listed in the indications for use section should be selected.
Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
Careful preoperative planning should include construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.
Prior to system use, the patient is brought into the OR, anesthetized, and positioned onto an Allen Advance, Jackson, or equivalent radiolucent OR table.

INTRAOPERATIVE MANAGEMENT

Follow the procedure detailed in the Valence Robotic Navigation System Operator Manual.

The patient is placed in a prone position that is appropriate for the planned procedure and that will provide access to the anatomy of interest and sufficient stabilization for conducting the procedure.
The sterile disposables are brought into the OR, and the sterile barrier on their packaging is examined to ensure a good seal.
The sterile reusable instruments are brought into the OR inside the sterilization container.
Roll in the Valence Robotic Navigation System and lock the wheels for stability, if desired.
Position the Camera in the preferred position for the procedure.
Sterile drape the Camera and Positioning Arm.
Attach the Targeting Platform to the end of the Positioning Arm.
Sterile drape the Targeting Platform.
Perform the imaging system scan using the desired technical parameters.
Allow the Valence Robotic Navigation System to perform automatic registration.
Plan the surgical procedure.
Use the targeting system to place the planned screw(s).

⚠ CAUTION: If an intraoperative situation requires immediate access to the patient, remove all instruments from the Guide Tube Assembly (if present), unlock the Positioning Arm carrying the Targeting Platform, and reposition it away from the surgical field.

POSTOPERATIVE MANAGEMENT

When use of the Targeting Platform and Camera is complete, remove drapes and cables to prepare the system components for cleaning and sterilization.
Power off the Valence System by pressing and holding the power button on the Control Unit for 2 seconds.
Clean the undraped Targeting Platform, Camera assembly and accessory equipment.
Follow the instructions in the section “Reprocessing of Reusable Equipment.”
Place the cleaned Targeting Platform, Strain Relief Box, Control Unit and Cable, Camera, Positioning Arms, Bed Rail Adapters, and all system cables securely in the drawers of the System Cart.

Power down the system computer and disconnect the main power cable from the AC outlet. Inspect the cable for any potential damage. Also ensure to disconnect the Ethernet Cable from the 3D imaging system if not previously done.

REPROCESSING OF REUSABLE EQUIPMENT

General Procedure

Do not allow fluid to enter any system enclosure. Do not spray liquids directly on the system. This can lead to equipment damage. Disconnect from power and allow the system to dry if you suspect fluids may have entered any part of the unit.

Power down and unplug the system before performing cleaning or disinfection procedures. Refer to the table below for compatible disinfectants and recommended chemistries. If a premoistened wipe is not available, use a clean wipe and moisten with the disinfectant. Do not over-saturate the wipe so much that liquid can enter openings in the parts to be cleaned. Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue on the system components. This will help maintain the appearance of the system components.

Disinfectant type	Disinfectant level
Quaternary ammonium germicidal detergent solution	Low level
Isopropyl alcohol (70%)	Low level
Phenolic germicidal detergent solution	Low level
Sodium hypochlorite (5.25% to 6.15%)	Low level

Cleaning the Targeting Platform, Control Unit, Strain Relief Box, and Camera

WARNINGS	None.
CAUTIONS	None.
Limitations on Reprocessing	Repeated reprocessing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Containment and Transportation	No particular requirements.
Preparation for Cleaning	Power down, unplug the system, and remove sterile drapes before performing cleaning or disinfection procedures.
Automated Cleaning	No particular requirements.

Manual Cleaning	Wipe and clean the exterior surfaces of the Targeting Platform, Control Unit, Strain Relief Box, Power and Network Unit, and Camera with a moistened low-level disinfectant wipe per the manufacturer's instructions. Do not damage the blue tape that seals the opening of the Targeting Platform. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible soil. If soil is present, repeat cleaning.
Drying	If necessary, dry the device with a clean, lint-free towel.
Maintenance Inspection Testing	Preventive maintenance is performed by authorized hospital or ATEC personnel only.
Packaging	No particular requirements.
Sterilization	No particular requirements.
Storage	No particular requirements.

- Unmount the Targeting Platform and the Camera from the respective Positioning Arms.
- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.

Cleaning the Positioning Arm

- Make sure that the ball joints of the Positioning Arm are free from debris.
- Wipe and clean the exterior surfaces of the Positioning Arm with a moistened low-level disinfectant wipe per the wipe manufacturer's instructions.
- If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer.
- The contact time refers to the minimum amount of time the surface needs to remain visibly wet.
- Use additional wipes, if needed, to maintain continuous contact time with the disinfectant.
- Examine the surfaces for visible soil. If soil is present, repeat cleaning.
- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.
  WARNING: Do not autoclave the Positioning Arm. It may degrade its holding capacity and result in patient injury.

Cleaning the Targeting Platform Cable Set, Control Unit Cable, Power and Network Cable

WARNINGS	None.
CAUTIONS	Do not allow liquid to enter the interior surfaces of the connector.
Limitations on Reprocessing	Repeated reprocessing has minimal effect on these cables. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Containment and Transportation	No particular requirements.
Preparation for Cleaning	Power down and unplug the system before performing cleaning or disinfection procedures. Unplug external cables.
Automated Cleaning	No particular requirements.

Manual Cleaning	Clean the cable by wrapping a low-level disinfectant wipe completely around the cable starting at one connector. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible soil. If soil is present, repeat cleaning. Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.
Drying	If necessary, dry the cables with a clean, lint-free towel.
Maintenance Inspection Testing	Ensure cable pins are not obstructed by particles that can compromise a proper connection. Other preventive maintenance steps are performed by authorized personnel only.
Packaging	If necessary, dry the cable with a clean, lint-free towel.
Sterilization	If necessary, dry the device with a clean, lint-free towel.
Storage	If necessary, dry the device with a clean, lint-free towel.

Cleaning the Main Power Cord

WARNINGS	None.
CAUTIONS	None.
Limitations on Reprocessing	Repeated processing has minimal effect on this cable. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Containment and Transportation	No particular requirements.
Preparation for Cleaning	Power down and unplug the system before performing cleaning or disinfection procedures.
Automated Cleaning	No particular requirements.
Manual Cleaning	Clean the power cable by wrapping a low-level disinfectant wipe completely around the cable. Wipe the cable from the plug end toward the back of the System Cart. Ensure contact with the plug, bend relief, and cable. Do not wipe the metal prongs on the plug. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant.
	Examine the surfaces for visible soil. If soil is present, repeat cleaning. Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.

Drying	If necessary, dry the cable with a clean, lint-free towel.
Maintenance Inspection Testing	Preventive maintenance is performed by authorized personnel only. Inspect the cable for any potential damage.
Packaging	If necessary, dry the cable with a clean, lint-free towel.
Sterilization	If necessary, dry the cable with a clean, lint-free towel.
Storage	If necessary, dry the cable with a clean, lint-free towel.

- Power down and unplug the system before performing cleaning or disinfection procedures.
- Clean the power cable by wrapping a low-level disinfectant wipe completely around the cable.
- Wipe the cable from the plug end toward the back of the System Cart.
- Ensure contact with the plug, bend relief, and cable. Do not wipe the metal prongs on the plug.
- If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer.
- The contact time refers to the minimum amount of time the surface needs to remain visibly wet.
- Use additional wipes, if needed, to maintain continuous contact time with the disinfectant.
- Examine the surfaces for visible soil. If soil is present, repeat cleaning.
- Ensure the cable pins are not obstructed by particles that could block, prevent, or compromise cable connections. Inspect the cable sheath and connector for any possible damage.
- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.

STERILIZATION AND RESTERILIZATION
REPROCESSING OF REUSABLE INSTRUMENTS

Affected components: Registration Array; Navigated Guide Tube, Standard, Robot; Navigated Guide Tube, NM, Robot; Awl, Robot; Awl Tap Cap; Instrument Tracker; Slap Hammer, Small; 4.5mm Awl Tap, Robot; 5.5mm Awl Tap, Robot; 6.5mm Awl Tap, Robot; 7.5mm Awl Tap, Robot; Tissue Protector, M Teeth; Tissue Protector, S Teeth; Tissue Protector, M Teeth, NM; Tissue Protector, S Teeth, NM; Insulating Sleeve, NM, Robot; TP Dilator, M Conical Tip, Robot; TP Dilator, S Conical Tip, Robot; Polyaxial Screwdriver, MIS, Robot; Reduction Screwdriver, MIS, Robot; Modular Shankdriver, MIS, Robot; 3.5mm Drill, Robot; 35mm SingleStep Stylet, Robot; 40mm SingleStep Stylet, Robot; 45mm SingleStep Stylet, Robot; 50mm SingleStep Stylet, Robot; 55mm SingleStep Stylet, Robot; Open Reduction Screw Clip-On; 8 mm Hex Driver, Reference Link; PSIS Pin 125; Camera Shroud; Scalpel Handle, Robot; Scalpel Handle, NM, Robot; Instrument Lid, Instrument Case Insert, Instrument Case.

General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the *CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008."*
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 "Water for the reprocessing of medical devices, 2014"* for example, DI/RO water.

Instrument Preparation and Disassembly:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to sterilization.
- Certain instruments may be disassembled prior to cleaning.

Cleaning of Instruments, Containers, and Trays:

- Instruments provided in a set must be removed from the set and cleaned prior to sterilization. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely.

Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.
• Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
• All solutions for cleaning must be prepared per the manufacturer's instructions.
• Use of water with high mineral content should be avoided.
• Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
• Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles/knobs from the shafted instruments prior to cleaning.
• Ensure all moving parts of instruments are cleaned at both extents of travel. Handle all products with care. Mishandling may lead to damage and possible improper function.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for Instruments (Required)

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using an appropriately sized soft bristled brush, such as a *Spectrum Surgical code #M-16* or 45-542 (or equivalent), to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard-to-reach areas and repeat 3 times.
Step 4	Rinse devices in Deionized / Reverse Osmosis (DI/RO) water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as *Prolystica® 2X Concentrate Alkaline Detergent,* per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with DI/RO water to remove all detergent residues.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulations, lumens, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	Prewash with cold tap water for 2 minutes.
Step 3	Enzyme wash using cleaner such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 4	Detergent wash using detergent such as Prolystica® 2X Concentrate Alkaline Detergent or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 5	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 15 seconds.
Step 6	Purified water rinse, hot (66°C/150°F minimum), for a minimum 10 seconds.
Step 7	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.

INSPECTION:

- Inspect each instrument, container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Inspect instruments for any other damage, wear, and/or corrosion.

STERILIZATION AND RESTERILIZATION:

- All instruments are provided non-sterile and must be steam sterilized prior to use in the provided trays using the validated cycle parameters in the table below.
- Alphatec perforated trays have been validated to achieve a sterility assurance level (SAL) of 10-6 using FDA cleared sterilization accessories (containers and filters). FDA cleared reusable or paper filters should be used to achieve and maintain sterility after processing.
- Alphatec perforated container/tray configurations have also been validated to a sterility assurance level (SAL) of 10-6 using FDA cleared sterilization wrap. Perforated container/tray configurations must be double wrapped to allow steam to penetrate and make direct contract with all surfaces.
- Do not stack trays during sterilization.
- Instrument sets have been validated in standard configurations. **No additional items should be added to the set for sterilization.**

Sterilization Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Instrument Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes	75 Minutes

Sterilization Notes:

- These parameters are consistent with the appropriate version of *ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."*

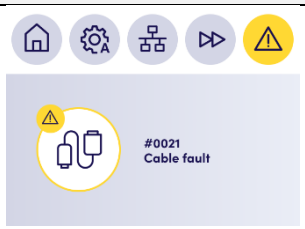
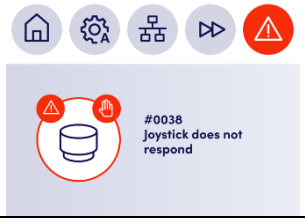
RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

SYSTEM OPERATION AND TROUBLESHOOTING

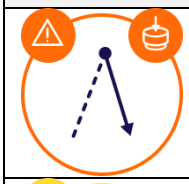
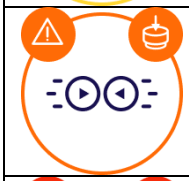
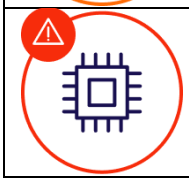
Control Unit Error Levels

If the error or warning symbol on the Targeting Platform lights up, refer to the Control Unit screen for additional error indications.

Exception Screen	Details
	**Auto Recovery Exception** An error occurred and is indicated by a symbol followed by an error code. Definitions of the symbols you find in section 2.1.2.2. For definitions of the error codes, refer to “Control Unit error codes” in section 5. The notification automatically disappears when the error condition is resolved (for example, plugging in disconnected cables).
	**Confirmable Exception** An error or notifiable event occurred, as indicated by the symbol. An error code, if applicable, provides detailed identification. For definitions of the symbols, refer to “List of warnings and error symbols” on page 106. For definitions of the error codes, refer to “Control Unit error codes” in section 5. After checking or resolving the cause of the notification, press the joystick to confirm. When the error condition is resolved, the notification disappears. For example, the notification indicating a change to the current plan will disappear after the joystick is pressed. If the visual indicators of the Targeting Unit are not working, the warning symbol is displayed. This indicates limited functionality. However, the workflow can continue.
	**Stop Exception** For definitions of the symbols, refer to “List of warning and error symbols” on page 106. No further operation is possible. Restart the Control Unit. If this notification is recurring after a restart, contact ATEC for technical support.

List of warning and error symbols

The error number #### displayed on the screen next to the symbol is root cause dependent and provides additional information if problem escalation is required.
For definitions of the error codes, refer to “System Error Codes on the Control Unit”.

Icon	Description	Type of exception
	Surgical plan has been changed; confirmation is necessary.	Confirmable Exception
	Cable fault or self testing	Auto Recovery
	Collision warning	Confirmable
	In combination with a stop icon  : Joystick hardware fault. No further operation possible. If this notification is recurring after a restart of the Control Unit contact ATEC. In combination with a confirm icon  : Joystick user error. Release the joystick to its center position and retry the procedure.	Stop Exception or Auto Recovery
	Enable button fault	Auto recovery
	Targeting Platform LED fault After confirmation, the system continues in emergency behavior mode.	Confirmable Exception
	Hardware fault	Stop Exception

Icon	Description	Type of exception
	Service needed	Stop Exception
	SD card error	Confirmable
	Configuration error	Stop Exception
	Lost communication with external planning station during movement to plan	Auto Recovery

The user can continue operation in an emergency behavior mode if they acknowledge the exception by pressing the joystick. This symbol on the Control Unit permanently indicates that mode.

Once acknowledged, the user can obtain reachability and alignment information from the display of the Control Unit.

System Error Codes on the Control Unit

List of error code IDs and their meanings:

ID	Exception	Exception Type	IFU entry (Service Manual entry) Required User Action
EX_01	TP µC Heartbeat signal missing	Recover/Stop	Check cabling and wait for recovery. See note at the end of the table
EX_03	MOVE command in TP but no valid MOVE_ENABLE	Recover/Stop	Check cabling and wait for recovery. See note at the end of the table
EX_04	Rotary encoder fault	Recover/Stop	Wait for recovery for a few seconds, system will perform self-test and continue if possible.
EX_08	A break condition in one module doesn't stop the other module.	stop exception	If a restart does not solve the issue, contact technical support
EX_09	Max. Motor current exceeded	confirmable exception	1. Release the Enable button and check the end-effector region for possible mechanical collisions. 2. Remove any obvious obstacle and re-position the Valence Targeting Unit. 3. Confirm the solution by pressing on the joystick.
EX_11	Self-test running Please wait	Recover/Stop	Wait for recovery for a few seconds, system will perform self-test and continue if possible.
EX_13	Deviation detected between linear and rotary encoder	stop exception	If a restart does not solve the issue, contact technical support

ID	Exception	Exception Type	IFU entry (Service Manual entry) Required User Action
EX_15	Self-test running Please wait	Recover/Stop	
EX_16	Missing signal from LED indicators	confirmable exception	Confirm via joystick. Continue working and contact technical support. Also check note at the of the table in IFU.
EX_17	EEPROM data corrupted or missing	stop exception	If a restart does not solve the issue, contact technical support
EX_18	Reference voltage fault	stop exception	If a restart does not solve the issue, contact technical support
EX_19	Inconsistencies in the detected HW and SW versions	stop exception	If a restart does not solve the issue, contact technical support
EX_21	Cable fault	auto recovery exception	Check cabling of Targeting platform and wait for recovery. Also check note at the of the table in IFU.
EX_23	Cabling fault on the Move Enable button	auto recovery exception	Check cabling and wait for recovery. Also check note at the of the table in IFU.
EX_25	LCD read display ID failed	continue with emergency flag (without confirmation)	The emergency LED on TP will turn on Also check note at the of the table in IFU.

ID	Exception	Exception Type	IFU entry (Service Manual entry) Required User Action
EX_26	Unable to read control unit display status	continue with emergency flag (without confirmation)	see above entry for EX_25
EX_27	Control unit display backlight fault	continue with emergency flag (without confirmation)	see above entry for EX_25
EX_28	Move Enable button stuck	auto recovery exception	Release button, if pressed, then confirm via joystick Otherwise, contact technical support
EX_30	Memory Card Error	confirmable exception (only once per power up cycle)	Confirm via joystick. Continue working and contact service if error appears frequently
EX_37	Firmware unable to identify ANG and POS module	stop exception	If a restart does not solve the issue, contact technical support
EX_38	Joystick does not respond	stop exception	If a restart does not solve the issue, contact technical support
EX_39	Joystick is not in central position	auto recovery exception	Center the joystick, exception should disappear. If exception is still on, turn off Control unit, check if joystick is in central and power up the system again.
EX_44	No CU Firmware available or bootloader CRC check failure	stop exception	ErrList: If a restart does not solve the issue, contact technical support
EX_45	ASP communication protocol error	auto recovery exception	Check cabling and wait for recovery Also see the note at the end of this table
EX_46	Version incompatibility between robot and control unit	stop exception	If a restart does not solve the issue, contact technical support

ID	Exception	Exception Type	IFU entry (Service Manual entry) Required User Action
EX_50	SL communication protocol error	Confirmable exception	Confirm via joystick. Continue working and contact service if error appears frequently.
EX_60	Plan changed	confirmable notification	Confirm new plan via joystick and note that Valence is now focusing on the new plan which is selected on the planning station.
EX_61	Re-powering from EMC Silent Mode fails	auto recovery exception	Check cabling and wait for recovery Also see the note at the end of this table
EX_63	Move Enable button pressed during boot-up	auto recovery exception	Release Move Enable button
EX_64	Motor movement without user command	stop exception	If a restart does not solve the issue, contact technical support
EX_65	Inconsistent parameters between AND and POS module	stop exception	If a restart does not solve the issue, contact technical support
EX_66	Rotary encoder not detecting existing movements	auto recovery exception	Confirm via joystick. Continue working and contact technical support if the error appears frequently
EX_72	Robot firmware cannot start	Recover/Stop	Wait for recovery for a few seconds, system will perform self-test and continue if possible.
EX_75	Loss of connection to workstation during movement	auto recovery exception	Confirm that alignment was aborted Check network connection to the planning station

ID	Exception	Exception Type	IFU entry (Service Manual entry) Required User Action
			See note at the end of the table
EX_76	Generic stop exception	Stop exception	Contact technical support

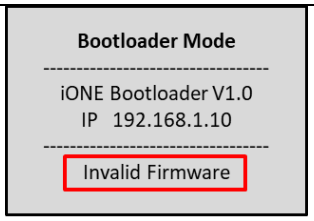
NOTE: for cabling errors 0001,0003, 0021, 0023, 0045, 0061:

1. Make sure all cables are connected properly.
2. After the cables are connected correctly, the exception will disappear automatically, and the system is ready for further operation.

Note: If no obvious connection problem can be found it might be an internal cable fault. If this notification is recurring after a restart, contact technical support and provide the error code next to the error symbol.

No bootup: The Control Unit does not go into homing state

Symptom 1	Pressing of Stand-by button at Control Unit does not start the system.
Cause	Power supply issue.
Solution	1. Check system cabling, especially power cable of Power and Network Unit. 2. Check if green power LED on the Power and Network Unit is on. 3. Check if white Power on LED on the Control Unit is on.

Symptom 2	After startup, the Control Unit enters the bootloader mode and reports an invalid firmware.	
Cause	There is no valid firmware installed on the system.	
Solution	No further operation is possible. If this notification is recurring after a restart of the Control Unit, contact the technical support.	

Control Unit Display Inoperable

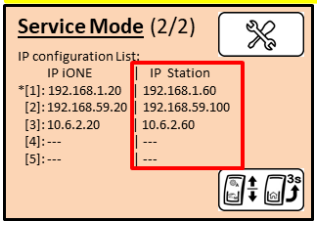
Symptom	There is no display on the Control Unit screen, but the system is still responding to user inputs. The power LED on Control Unit is green and indicates readiness.
Cause	There is a hardware failure on the Control Unit screen.
Solution	Continue working and contact ATEC for support. Note: The system is not able to show any information on the Control Unit screen, but the system is still able to perform all other tasks. You can continue operation in emergency behavior mode. You can obtain reachability and alignment information from the LEDs of the Targeting Platform.

Control Unit Indicates that no Reachability Information can be shown

Symptom 1	The Control Unit screen indicates that no reachability information can be shown The Control Unit shows the following icon:	
Cause	There is no active connection to Third-party image-guided surgery.	
Solution	Refer to section **Error! Reference source not found.**.	

No Communication with the Workstation

Symptom 1	The Control Unit screen indicates the network is not connected. 
Cause	The Ethernet cable is not connected to either the Third-party image-guided surgery system or the Power and Network Unit.
Solution	1. Connect the Ethernet cable. 2. Make sure the Third-party image-guided surgery icon appears on the Control Unit screen. 

Symptom 2	The Control Unit screen indicates that there is a connected network, but no Third-party image-guided surgery icon is present. 
Cause 1	Third-party image-guided planning software is not running.
Solution 1	Log into Third-party image-guided surgery and start software.
Cause 2	In case of Third-party image-guided surgery: The network settings are not correct.
Solution 2	Check the IP address of the Third-party image-guided surgery to which the Control Unit is configured for. The last used Third-party image-guided surgery IP address can be seen on the initialization screen during startup.  All possible Third-party image-guided surgery IP addresses are shown on page two of the service mode. Refer to section **Error! Reference source not found.**.  If the IP address of the used Third-party image-guided surgery is not in this list, adapt the current Third-party image-guided surgery network address settings according to the instructions for use provided with the product. Alternatively contact ATEC for support.

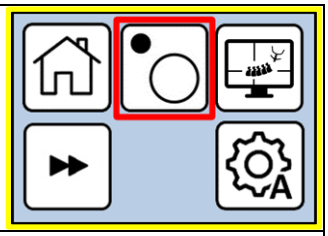
The System does not Execute Automatic Motion

Symptom 1	The Targeting Platform does not move when pressing the Move to Home button and one of the Enable buttons or .
Symptom 2	The Targeting Platform does not move when pressing the Move to Plan button and one of the Enable buttons or .
Cause	The Control Unit is set to Manual Mode. The Targeting Platform must be in Automatic Mode to move to the plan or to the home position.
Solution	If the Manual Mode icon displays on the Control Unit, press to change to Automatic Mode. Confirm that the Automatic Mode icon displays on the Control Unit:
Symptom 3	The Targeting Platform displays a warning, and the Control Unit screen shows the following symbol:
	Automatic alignment to surgical plan cannot be initiated.
Cause	The Navigated Guide Tube is not visible to the Camera.
Solution	Remove objects that may be blocking the line of sight between the Camera and the Navigated Guide Tube. Rotate the Navigated Guide Tube with retroreflective spheres so that the spheres are facing the Camera.

Control Unit indicates that the Surgical Plan has changed

Symptom 1	The Targeting Platform lights up the warning LED and the Control Unit shows the following notification:	
Cause	The surgical plan has been changed in the external station's software.	
Solution	If the surgical plan changed, press the joystick to confirm the change \. The system now shows reachability information for the new plan.	

The System is not Aligning with the Active Surgical Plan

Symptom 1	An automatic alignment to the plan does not start. The Targeting Platform and the Control Unit screen both display this symbol:  
Cause	The Targeting Platform is parked in a position from which it cannot reach the surgical plan.
Solution	Move the Targeting Platform to a different position. Move the Targeting Platform to its Home position. Unlock the Positioning Arm with one hand while holding the Targeting Platform with the other hand. Move the Targeting Platform until it displays the following symbol indicating that the platform can reach the active surgical plan:  Lock the Positioning Arm. Make sure that the Control Unit is in Automatic Mode. Press the Move to Plan button  and one of the enable buttons  or  .
Symptom 2	Alignment was started and the system stops close to the aligned position but is not showing the aligned symbol. The Control Unit displays the following symbol, indicating that the platform can reach the active surgical plan: 
Cause	The number of defined iterations for fine alignment was reached before a successful alignment was obtained. This can be caused by unfavorable tool visibility.
Solution	Ensure better visibility by rotating the tracker so that the spheres are facing the Camera or adjust the Camera position so that the tracker is visible. Start the alignment process again from the current position by pressing the Move to Plan button and one of the enable buttons  or  .

Sudden Loss of Connection between the Workstation and the Targeting System

Symptom	Disconnection of the Targeting System from the Workstation without automatic recovery. Loss of registration and navigation data.
Cause	Electrostatic discharge on the ethernet port while connecting or disconnecting the 3D imaging system.
Solution	Restart the Targeting System and re-establish communication between the Workstation and the Targeting System. Observe the displayed information in the Targeting Platform and the Control Unit. Perform a new automatic registration, if necessary. Do not proceed without confirming the accuracy of the displayed information.

SERVICE

Corrective Maintenance

If the instructions in the Troubleshooting section do not solve the problem, contact ATEC for assistance. Technical service personnel will either assist to solve the problem immediately or inform you about the procedure for a replacement of the affected component. No corrective maintenance will be provided during patient treatment.

Recommended Maintenance

The system and its associated components should be inspected and tested annually at a minimum. Inspection and testing should be completed by an authorized and trained service person.

Contact ATEC or train a human resource in your facility to schedule a maintenance and system check appointment.

Inspection and testing should include the following:

- With the system powered off, visually inspect the system components, cables, and mechanical and electrical connections for damage, wear, and excessively loose fixation. If the mains power cord is damaged or degraded, first replace the power cord with original replacement parts. The drawers have to be removed to get access to the internal connectors.
- With the system powered on, verify functionality of the entire system including movement, movement prevention, button functionality, and software functionality.
- Be sure to re-install proper strain relieve of the power cord.
- Verifying basic safety of the system shall be performed in intervals of max. 24 months according to IEC62353 as defined below. This includes visual inspection, ground bond, hi-pot testing, and verification of earth leakage currents.
- Hi-Potential (Hi-Pot) — To test for adequate insulation from line and neutral to ground, apply a high-potential voltage to line and neutral with reference to ground.
- Perform this test with the system powered off. Attach the test equipment to the system power cord. Attach the return lead to ground. Apply Hi-Pot voltage to line and neutral. This test can be performed either with 1500V for 1 minute or with 1800V for 10 seconds. Make sure that you do not touch the equipment during the test.
- Ground Integrity — To test for adequate grounding of equipment, apply a high current through the protective earth conductor to the enclosure. Perform this test with the system powered off. Subsequentially attach the test lead to the exposed metal on the left and the right-side rails and verify that impedance does not exceed 0.2 Ohms.
- Earth Leakage Test — Earth leakage current tests have to be performed in accordance with IEC60601 or IEC62353. Even the mandatory limits for this are 5mA for normal case condition (NC) and 10mA for Single Fault Conditions (SFC), the expected earth leakage currents for both test conditions shall not exceed 0.5mA since this would indicate a structural fault of the mains power supplies in the system. If values are exceeded, power supplies in the system shall be exchanged.
- Perform this test with the system powered on. Plug the system power cord into the Earth Leakage tester.

Software Updates

Software updates and patches will be installed by qualified ATEC service technicians when required.

Replaceable Parts

System cables (specifically the Targeting Platform Cable Set, Control Unit Cable, Power and Network Unit Cable, Power Cords, and the external CAT6 Ethernet Cable for connection with the 3D imaging system) and Positioning Arms are replaceable system parts.

Disposal

Do not dispose of the system or system components in the unsorted municipal waste stream. Observe local regulations concerning disposal of system components.

SPECIFICATIONS

U.S. Food and Drug Administration Classification

The product is a Device Class 2, Product Code: OLO
Classification Name: Orthopedic Stereotaxic Instrument
Regulation Number: 882.4560
Submission Type: 510(k) Class II (performance standards)

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

The electromagnetic system has been successfully tested against the requirements of IEC 60601-1
General Requirements for Basic Safety and Essential Performance, and the associated Part 2 Collateral Standard, Electromagnetic Compatibility where applicable.

Electromagnetic Emissions and Immunity Declarations

Electromagnetic emissions			
Valence™ is intended for use in the electromagnetic environment specified below. The customer or the user of Valence™ should ensure that it is used in such an environment.			
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**	
RF Emissions CISPR 11	Group 1	Valence™ uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	Valence™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A		
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±2kV, ±4kV, ±6kV, ±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input / output lines	±2kV for power supply lines ±1kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±0.5, 1kV line to line ±0.5kV, ±1kV, ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T for 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º <5% U_T for 1 cycle at 0º 70% U_T for 25 cycles at 0º	<5% U_T for 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º <5% U_T for 1 cycle at 0º 70% U_T for 25 cycles at 0º	Mains power quality should be that of a typical commercial or hospital environment.

	<5% U_T for 250 cycles at 0º	<5% U_T for 250 cycles at 0º	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	3, 30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	65 A/m, 134.2kHz 7.5 A/m, 13.56 MHz	65 A/m, 134.2kHz 7.5 A/m, 13.56 MHz	N/A
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 V_{RMS} 150kHz to 80 MHz 6V_{RMS} ISM bands[a]	3 V_{RMS} 150kHz to 80 MHz 6V_{RMS} ISM bands[a]	Portable and mobile RF communications equipment should be used no closer to any part of Valence™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 2.33\sqrt{P}$ 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.7 GHz	3 V/m 80MHz to 2.7 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters. such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio. AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Valence™ is used exceeds the applicable RF compliance level above, Valence™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Valence™ .

[d] Over the frequency range 150kHz to 80 MHz. field strengths should be less than 3 V/m.

Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Modulation	Test Level	Compliance Level
385	380 to 390	Pulse, 18Hz	27 V/m	27 V/m
450	430 to 470	FM, ±5kHz	28 V/m	28 V/m
710	704 to 787	Pulse, 217Hz	9 V/m	9 V/m
745				
780				
810	800 to 900	Pulse, 18Hz	28 V/m	28 V/m
870				
930				
1720	1700 to 1990	Pulse, 217Hz	28 V/m	28 V/m
1845				
1970				
2450	2400 to 2570	Pulse, 217Hz	28 V/m	28 V/m
5240	5100 to 5800	Pulse, 217Hz	9 V/m	9 V/m
5500				
5785				

Recommended separation distances between portable and mobile RF communications equipment and Valence™

Valence™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Valence™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Valence™ as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.22
0.1	0.37	0.37	0.71
1	1.17	1.17	2.23
10	3.70	3.70	7.05
100	11.70	11.70	22.30

WARRANTY

The system is covered by a warranty of 12 months.

TECHNICAL DATA

Essential Performance

No unintended movement of the system is allowed. Under all conditions, the move enable button has to be controlled by the operator to allow any movement.
The system shall support the application of external forces on the Targeting Platform equal to or lower than 30N with a deviation between the pre-load and post-load positions equal to or lower than 1.0mm at the maximum distance of 100mm from the Targeting Platform Assembly.
Interrupted system operation due to expected environmental disturbances shall be recoverable automatically or with user interaction in less than 1 minute.

- *The system may not change the operating state due to influence of any electromagnetic phenomena as defined in EN60601-1-2.*
- *During active state, short term flickering (<1 second) of the display on the Control Unit is allowed as long as it returns to the previous state without any user interaction. It is not allowed that an outdated status is displayed or the display is "frozen" without obvious recognition by the user. Frozen state with obviously damaged display content, or no display at all, is not regarded as safety relevant.*
- *The blue ALIGNED LED has to be turned on by repetitively updating the status. Static or one time signaling shall not keep the LED on for more than 100ms.*
- *The orange WARNING LED symbol is designed to turn on immediately, by hardware, in case of any unresolved problem or missing heartbeat of the Targeting Platform.*
- *The movement to a planned target shall not be interrupted by any electromagnetic interference.*
- *No unintended movement of the system is allowed. Under all conditions, the move enable button has to be controlled by the operator to allow any movement.*
- *Manual movement of the Targeting Platform with the joystick shall be possible under all worst-case EMC conditions.*
- *It shall be possible to repetitively hit a target point of 1mm diameter at the maximum distance of 100mm below the Targeting Platform end effector (lower rotation axis), based on the internal sensor system.*
- *The system shall support the application of external forces on the Targeting Platform equal to or lower than 30 N with a deviation between the pre-load and post-load positions equal to or lower than 1.0 mm at the maximum distance of 100mm from the Targeting Platform end effector.*

Intended Environment for Use

The intended user environment for the system is 10-30°C, 30-70% relative humidity (RH), non-condensing, and an atmospheric pressure of 0.689bar-1.019bar.
The system is tested for use only in operating room environments. The system is not suitable for use in any type of vehicle or aircraft.
The system is not suitable for magnetic resonance therapy environments.
The system is used in any typical environments including all radiofrequency wireless bands defined in Table 9 of IEC60601-1-2:2014.
The system is not required to be used only in shielded location special environments.

Cable Specifications

Targeting Platform Cable Set, maximum length 2.8m, shielded cable, SELV only.
Control Unit Cable, maximum length 6m, shielded cable, SELV only.
Power and Network Unit Cable, maximum length 6m, shielded cables, SELV only.
Network cable for connection with the Workstation, maximum length 20m, shielded, CAT 5e or better.
Power cord, various versions of national cords sets, non-shielded, maximum length 5m.

Note: The connectors are uniquely shaped, and therefore, it is not possible to plug a cable into the wrong connector. To facilitate finding the correct connector, each plug-receptacle combination is color coded.

Technical Specifications

Operating temperature (without camera)	10–30°C (50–86°F)
Operating temperature (with camera)	18–25°C (64.4–77°F)
Operating relative humidity	30-70%, non-condensing
Operating pressure	0.689 bar–1.019 bar
Operating altitude	Up to 3000 m (9842 ft)
Shipping temperature	0–40°C (32–104°F)
Shipping relative humidity	20–80%, non-condensing
Shipping pressure	0.689 bar–1.019 bar
Storage temperature	0–30°C (32–86°F)
Storage relative humidity	20–80%, non-condensing
Storage pressure	0.689 bar–1.019 bar
Input voltage	100–240 VAC
Input frequency	50/60 Hz
Fuse rating	2A 250 V Radial 8.5 mm × 4.0 mm × 8.0 mm, Slow Blow
Maximum power	15 VA
Electrical Safety Classification IEC 60601-1	Class I, continuous operation with CF (Cardiac Floating) applied part, equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

Movement	±2 cm from home position (Targeting Platform)
Maximum load	Targeting Platform: 20 N (4.5 lbf) without interruption of motion; halt at 40 N (8.9 lbf) Positioning Arm: 52 N (11.7 lbf) of vertical force without slippage when fully extended. Return to the original position with less than 1.0mm error when a 30N load is applied
Software Classification	Class B (per IEC 62304) and Major Level of Concern (per FDA Guidance)
RoHS compliance	Yes
Max. Inrush Current	40A/230VAC

Targeting Platform specifications

Dimensions (L x W x H)	216 mm x 125 mm x 74 mm
Weight	1.6 kg
Classification of installation and use	Portable
Mode of operation	Continuous
Relative Accuracy	0.03mm
Absolute accuracy	0.2mm
Range of motion	±2 cm from home position (Targeting Platform), 25º in angulation around center axis

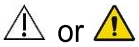
Control Unit specifications

Dimensions (L x W x H)	267 mm x 144 mm x 79 mm
Weight	830 g
Classification of installation and use	Portable and Handheld
Mode of operation	Continuous
Side-rail compatibility	EU, UK, US (per EN 60601-2-52:2010)

SYMBOLS

Explanation of Symbols on Package and Device Labeling

The following symbols may appear on system equipment, on system packaging, on accessories used with the system, or in this document.

Symbol	Definition	Symbol	Definition
	Manufacturer		Date of manufacture
	Use by date		Consult instructions for use.
	Atmospheric pressure limitation		Follow Instructions for use.
	Unique Device Identifier		MR unsafe
	Caution		Serial Number
	WEEE (Waste of Electrical and Electronic Equipment)		Batch code
	Catalogue number		Quantity
	Not made with Natural Latex Rubber	 For non-sterile components	Do not use if package is damaged
	Do not Re-sterilize	 For sterile components	Sterile if packaging is undamaged and unopened
	Single Use Only Disposable		Sterilized using ethylene oxide
	Temperature limit		Relative humidity limit
	Applied Part (Type CF)		Power button
	Network Cable connection interface on the Power and Network Unit		Protective Earth (ground)
	Angulation button		Positioning button
	Fast speed		Slow speed
	Automatic Mode button		Manual Mode button

	Move to Plan button		Home button
	Do not autoclave		Targeting Platform in home position
	Targeting Platform not in home position		No reachability information available.
	The system cannot reach the current plan. Automatic alignment is not possible.		The system can reach the current plan. Automatic alignment is allowed.
	Trajectory aligned and Move to Plan finished.		Deviation detected in Motion Monitoring Mode. Both icons are alternating flashing.
	Tool or reference frame is not visible, navigation not possible.		No network connection is available or established.
	Network connection established with peripheral device, but no connection to the external Workstation.		Communication with the Workstation is successfully established.
	Warning icon on the Control Unit. An exception has occurred. The reason of the warning is indicated by a dedicated icon and error code.		Warning indicator for emergency behavior mode.
	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.		Non-sterile.
	The device is compliant with applicable directives and regulations for CE-Marking.		Medical Device

CONTACT INFORMATION

If a serious incident occurs related to the use of this system, report it to ATEC Spine Customer Service using any of the methods listed below.
Provide the following information when escalating a problem:
Serial number of the system
Batch code of the affected item (if applicable)
Contact information (name, email address, and phone number)
Installation site (hospital name and address)
Contact at the hospital for shipments

Name and address:
ATEC Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 U.S.A
Phone: +1 800-922-1356
Fax: +1 800-431-9722
E-Mail: customerservice@atecspine.com

COPYRIGHT STATEMENT

℞ Only